

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Name of Product: aca® *plus* FT4 Calibrator

FDA Classification Name: Calibrator

Predicate Device: Abbott Laboratories*IMx® Free T4 Calibrator

Device Description: The FT4 Calibrator is a lyophilized human serum-based product. The Level 1 calibrator contains no detectable thyroxine. The kit consists of six vials two at each of three levels.

Intended use: The aca® *plus* FT4 Calibrator is intended to be used on the aca® *plus* immunoassay system to calibrate the Free Thyroxine (FT4) Method.

Comparison to Predicate Device:

<u>Item</u>	<u>aca® <i>plus</i> FT4 Calibrator</u>	<u>IMx® Free T4 Calibrator</u>
Intended Use	Calibrator	Calibrator
Analytes	thyroxine	thyroxine
Matrix	human serum base	human serum base
Form	lyophilized	liquid
Volume	3.0 mL per vial, reconstituted	4.0 mL per vial
Levels	3 levels	6 levels

* IMx® is a trademark of Abbott Laboratories, Abbott Park, IL 60064